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TITLE: Medical Device Plug-and-Play Interoperability Standards and Technology Leadership

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14. ABSTRACT
This BAA is providing core program support to develop key capabilities of the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program to lead medical device interoperability to support clinical solutions for improving patient safety and healthcare efficiency. Under MD PnP program leadership during the past year, a multi-institutional/industry working group submitted to FDA a Pre-IDE regulatory submission of a safe integrated medical device system; an updated version of the MD FIRE procurement language was signed by the VA and posted on our public website; the Clinical Landscape & Needs subgroup of the newly formed and FDA-sponsored Medical Device Interoperability Coordinating Council collected and shared clinical scenarios; we contributed materially to UL's proposed standard for certifiable safety of medical device interfaces; we collaborated with the VA, NIST, NSF, ONC, and others, including work with AAMI on standards and smart alarms initiatives.

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Award Number W81XWH-09-1-0705
Principal Investigator: Julian M. Goldman, MD
Period of Performance: 21 September 2011 – 20 September 2012

[**Note**: The initial BAA award period was amended to end 20 September 2011, and the first option-year was exercised to run through 20 September 2012, with a no-cost extension through 20 March 2013. This report is an Annual Report covering the period of 21 September 2011 through 20 September 2012.]

Introduction

A May 2004 symposium jointly sponsored by TATRC and CIMIT kicked off what became the Medical Device "Plug-and-Play" (MD PnP) interoperability program. Initially focused on creating a standardization framework for interoperability of medical devices in the Operating Room of the Future (ORF), the program collected clinical requirements from anesthesiologists, surgeons, and clinical engineers, and began to define an agenda for standards development. Within a year, we acknowledged that the need for interoperability encompasses the full continuum of healthcare environments, and we developed a strategy to accelerate the development of interoperability technologies as well as standards. The strategy addressed the need for a "sandbox" laboratory environment to facilitate the testing of devices and technologies with proposed standards; the development of a "plug-and-play" system architecture; collaboration with regulatory agencies; leveraging standards and technology to address vendors' legal concerns; and assuring the clinical relevance of all proposed interoperability solutions.

TATRC support, through a prior BAA and conference grants, has enabled the MD PnP interoperability program to develop key capabilities, to identify and access numerous available resources, and to build collaborations to achieve MD PnP objectives. TATRC's commitment has enabled us to attract additional program funding from Partners Information Systems, CIMIT, NSF, NIST, and NIH. We have created a medical device interoperability lab at CIMIT in Cambridge, MA, as a multi-institutional, interdisciplinary shared resource. We have developed clinical use cases demonstrating the capability of medical device interoperability to improve patient safety and exhibited these at national meetings. We held an international conference on "Improving Patient Safety through Medical Device Interoperability and High Confidence Software", jointly sponsored by TATRC and NSF.

Significantly, core program support from TATRC enabled us to lead and achieve the writing and submission of the first medical device integration system standard – the Integrated Clinical Environment (ICE) standard, Part I, which includes functional architecture and risk mitigation strategies for networked patient-centric interoperable medical devices. In addition, we led a successful collaborative effort of three major healthcare providers to develop and adopt sharable interoperability contracting language for use in the procurement of medical devices and related equipment. We facilitated the endorsement by seven medical societies (including the American Medical Association) of medical device interoperability for improving patient safety. We worked with three companies on DoD SBIR projects to develop a first-responder ICE Supervisor. TATRC BAA support has been instrumental in providing "program glue" to effectively leverage these highly interdependent and synergistic activities to realize program objectives.

We planned and co-sponsored with the FDA and Continua Health Alliance a three-day workshop on Medical Device Interoperability in January 2010, attended by over 200 participants from industry, health care, and federal agencies. There has been a follow-on working group

meeting regularly, under MD PnP leadership, to address safety and regulatory concerns for integrated medical device systems. The FDA organized another meeting on device interoperability with AAMI in 2011, and in January 2012 the FDA formed a Medical Device Interoperability Coordinating Council to bring together various groups working on different aspects of interoperability – we have continued to play a leadership role in this activity.

Body of Report

The MD PnP Program has become a recognized leader in medical device interoperability to support clinical solutions for improving patient safety and healthcare efficiency. Interoperability will enable the creation of complete electronic health records and will introduce error resistance into networked medical device systems. We are producing a standardization framework consisting of a functional architecture and requirements for implementing standards in a manner that will support interoperability for effective clinical deployment. This requires critical evaluation (or "gap analysis") of potentially suitable candidate standards, as well as the modification of existing standards and development of new standards for implementation in the MD PnP standardization framework. By leveraging available standards, we expect to accelerate the MD PnP standards framework development, so that useful candidate standards can be vetted and demonstrated. This includes partnering with industry and the FDA to define interoperability-related hazards and their mitigations to help inform a regulatory pathway for networked medical device systems, as well as developing the MD PnP Lab as a "sandbox" populated with medical devices and test equipment to serve as a vendor-neutral environment to perform interoperability testing and conformance testing to evaluate proposed standards. Building on what has been accomplished to date, we have sought to leverage areas of traction around five key themes identified for this work:

- Standards development
- Open clinical platform development
- Clinical and engineering requirements for MD PnP
- Regulatory pathway
- Inclusion of device interoperability in the national health IT agenda

Since the program's inception, more than 850 clinical and engineering experts, and representatives of more than 120 companies and institutions have participated in our plenary workshops / conferences, working group meetings, and focus groups to contribute to ongoing program activities that helped shape the common goals. Our geographically dispersed, interdisciplinary, multi-institutional team of collaborators has included participants from: Kaiser Permanente, Johns Hopkins Medicine, the VA, FDA, NIST, TATRC, university computer and information science groups at Pennsylvania, Illinois/Urbana-Champaign, Kansas State, New Hampshire, Waterloo (Canada), and Wiener Neustadt (Austria), Draeger Medical Systems, Philips Healthcare, GE Healthcare, Hospira, Intel, DocBox Inc., Moberg Research Inc., Linea Research Inc., Anakena Solutions Inc., LiveData Inc., MITRE Corporation, Lockheed Martin Corporation, IXXAT, Draper Laboratory, NSF/CPS (Cyber Physical Systems), Geisinger Health System, and the Partners HealthCare System community (MGH Anesthesia, Biomedical Engineering at MGH and Brigham & Women's Hospital, and Partners HealthCare Information Systems).

For the first option-year period of this grant, we proposed the following objectives:

Standards Development
- Continue to convene working and writing groups for subsequent ICE standard parts (Parts II and III for the ICE network controller and device models); manage their work to produce draft standards for submission to ASTM Committee F29
- Expand the gap analysis work of the ICE-PAC group to include additional medical devices and clinical scenarios

Open Clinical Platform Development
- Develop device interface models, working with collaborators, and share requirements with manufacturers
- Coordinate outputs of collaborative projects with NIST, FDA, universities, CIMIT investigators, and industry partners to further open platform development

Clinical and Engineering Requirements for MD PnP
- Develop and deploy a web-based repository of interoperability-relevant clinical scenarios that will facilitate submission of new scenarios and sharing of data
- Continue detailed analysis of the most useful scenarios to define detailed workflows, clinical requirements, and related engineering requirements
- Identify appropriate use cases to include in subsequent ICE parts

Regulatory Pathway
- Publish jointly with FDA a summary of the results of the medical device interoperability workshop
- Work with industry to complete development of a prototype regulatory submission to FDA, as a test case for FDA regulation of systems of integrated medical devices

Facilitated Collaboration (Program Development and Management)
- Develop an enhanced collaborative website for the MD PnP collaborators group to publicly share information.
- Publish on the MD PnP website a second iteration of the MD FIRE contracting language, and work with additional healthcare delivery organizations to adopt MD FIRE
- Stay actively involved with national health IT developments to support inclusion of medical device interoperability on the agenda.

Research Accomplishments

Standards Development, Objective 1: Continue to convene working and writing groups for subsequent ICE standard parts (Parts II and III for the ICE network controller and device models); manage their work to produce draft standards for submission to ASTM Committee F29.

As the ICE conceptual model evolved, it became apparent that development of Parts II and III (device and system models, and the network controller) need to proceed in parallel, due to the interdependencies of the proposed requirements and functionality. It also became clear that certain complex technical issues required additional analysis in preparation for standards development. The pre-standards development of device models in particular requires broader collaboration and expertise, and work on our NIH project has further elucidated the complex requirements of device and system models, and the network controller. With this important work ongoing, we have achieved timely results through less formal working groups that are learning from real-world experience. For example, our MD PnP team participated extensively in the AAMI Ad-Hoc Group on Health Information Technology and Interoperability (AAMI/HITI) that

wrote a report for the AAMI Standards Board regarding the current state of interoperability and standards in the healthcare industry, and explored AAMI's potential role in medical device interoperability standards. An early draft of this AAMI/HITI report was shared with the Standards group at FDA, and the completed report was published by AAMI in January 2012. Our team also participated in the drafting of the New Work Item Proposal to develop a new standard for ICE-compliant system safety requirements for PCA infusions.

We are continuing our standards-related work through other multi-organizational working groups such as the Medical Device Interoperability Safety (MDIS) Working Group (see **Objective 9**) and the FDA-convened Medical Device Interoperability Coordinating Council (MDICC). Our collaboration with UL has resulted in mutual contributions to our architecture design and their new proposed standard (UL 2800) for certifiable safety of medical device interfaces. We continue to draw on requirements and architecture material from our NIH work to assist the efforts of these kinds of working groups, which are providing a forum for sharing our learnings from both the NIH Quantum work and the TATRC work relative to the gaps in existing standards and recommendations on how they can be improved.

Standards Development, Objective 2: Expand the gap analysis work of the ICE-PAC group to include additional medical devices and clinical scenarios.

The ICE-PAC work is essentially completed, in that the work of the new MDICC group (see **Objective 1**) includes a focus on gap analysis. Many of the same companies and federal agencies that have been involved in ICE-PAC – DocBox, Philips, MindRay, Baxter, FDA, Anakena, and NIST – are now involved in MDICC. This group, including Dr. Goldman's subgroup on Clinical Needs & Clinical Landscape (CNCL), is committed to reviewing the device interoperability landscape to identify relationships between different standards, including the gaps in meeting interoperability standards such as ASTM ICE.

Platform Development, Objective 3: Develop device interface models, working with collaborators, and share requirements with manufacturers.

Our team has been working on device interface requirements and device models, including a draft specification for a general ICE device interface model, as well as requirements for the ICE Network Controller and ICE medical device interfaces. We wrote an initial overview of some of the safety and privacy issues and requirements for ICE, which was presented at and published in the proceedings of the IEEE EMBS conference in September 2011. Our Device Models working group for the NIH project is further defining the attributes of device models, including the association (or set-up time) protocol, the real-time communication protocol, and the information or data model in collaboration with NIST. We are continuing to update and develop the Medical Device Interface Data Sheets (MDIDS) for point-of-care devices that are most commonly used in hospitals.

We have continued our analysis of device clock time-stamp data, which will also feed device models, system requirements, and standards work. A poster on preliminary data collected at MGH was shown at our Lab Open House in September 2011 and at the January 2012 meeting of the Society for Technology in Anesthesiology (STA), and was published in the STA Proceedings. In November we collected comparable data for Johns Hopkins and the Hospital of the University of Pennsylvania. We held a panel on medical device clock time issues at the FDA-AAMI standards meeting in March. Due in part to our research, standards requirements in the new Meaningful Use Part 2 Notice of Proposed Rule-Making, include the following:

> "(g) Synchronized clocks. The date and time recorded utilize a system clock that has been synchronized following Request for Comments (RFC) 1305 Network Time Protocol

(NTP) v3 (incorporated by reference in §170.299) or RFC 5905 NTPv4 (incorporated by reference in §170.299)."
http://www.healthit.gov/providers-professionals/meaningful-use-stage-2

In our ongoing analysis of device clock time-stamp data, we have been working with the Boston VA to collect additional data at their site. There have been some challenges, and we are still waiting for the delivery of the data, as we were not permitted by their protocols to collect the data with our own personnel. Our time-stamp data analysis will inform device model, system requirements, and standards work, and is already contributing to national discussions on the topic.

As we have developed device interface requirements and device models, we have discussed requirements for connectivity with various medical device manufacturers, most recently with Draeger, GE, and Hospira (for infusion pumps). This is an ongoing dialog that is mutually beneficial.

Platform Development, Objective 4: Coordinate outputs of collaborative projects with NIST, FDA, universities, CIMIT investigators, and industry partners to further open platform development.

We are continuing to leverage synergies among our projects and our collaborative relationships to ensure that all efforts contribute to the overarching goal of furthering medical device interoperability. Ongoing standards gap analysis, particularly joint systems engineering analysis with NIST, has been producing recommended updates to existing standards (IEEE 11073 and ICE Part 1).

We have been working with a team of engineers at Intel Corporation to identify and model clinical scenarios, including the PCA safety use case, in a variety of simulated hospital IT networks. This work is helping to clarify functional requirements for the ICE Network Controller and ICE External Interface, as well as safety requirements for the PCA scenario, such as the maximum number of pumps that can be managed reliably by a control application in an integrated clinical environment. Our initial work with Intel focused on modeling bandwidth and latency in a simulated interoperable ICU and advanced OR. This first study has been completed and published in *IEEE BI&T*. We are negotiating the next phase of work with Intel, and are considering modeling wireless networks and the processor load implications of various ICE architectural choices. This project is also helping Intel with requirements for their roadmap, which will support adoption of device interoperability.

In our CIMIT PCA safety interlock project, we have been utilizing the BeagleBoard as an inexpensive, open source development platform, and several of our collaborators are using these boards as well. We have added a network time protocol (NTP) client and server to the PCA prototype system, in order to provide a trusted master time reference. Learnings from this project are informing our more general platform work as well as our standards work.

Clinical and Engineering Requirements, Objective 5: Develop and deploy a web-based repository of interoperability-relevant clinical scenarios that will facilitate submission of new scenarios and sharing of data.

Objectives for this option-year include completing requirements for this use case repository, and obtaining feedback from FDA, NIST, and AAMI. We have been working on the framework for use case collection, analysis, and reporting, most recently in the context of the FDA-sponsored MDICC (see **Objective 6**). The work on redesigning our early prototype database resumed in

May, when a new engineer joined our team. Requirements are being finalized. The next steps, covered in our new award from TATRC, will be to build, test, and deploy a more robust web-based implementation of the use case repository.

Clinical and Engineering Requirements, Objective 6: Continue detailed analysis of the most useful scenarios to define detailed workflows, clinical requirements, and related engineering requirements.

The clinical use cases we have collected are being used as highly-valued input for work by our industry and university collaborators, and several archetypal use cases representing different aspects of interoperability were included in Annex B of the ICE standard, Part I. Four use cases that are intended to represent a broad spectrum of interoperability requirements have been selected for the NIH project: (1) Medication safety interlock, exemplified by Patient Controlled Analgesia (PCA) infusion pump safety interlock; (2) Optimization of Intensive Care Unit (ICU) preparedness for patient transfer from OR, exemplified by preparing the ICU (devices, medications, personnel) to receive a post-op patient after cardiac surgery; (3) Use of telehealth devices when a patient enters the hospital, including integration into Electronic Health Records (EHRs); and (4) Sedation during Endoscopy, demonstrating safety and effectiveness implications of deploying increasingly complex interoperable medical device systems.

Collaborative work with DocBox Inc. and with our NIH collaborators, under other funding, is contributing to the refinement of project-specific clinical requirements and use cases. This effort is yielding detailed workflow and requirements from an engineering perspective, and is expected to feed back additional details into the workflow documentation.

The activity of identifying and refining high-level clinical scenarios, in order to lay the foundation for developing technical specifications for medical device interoperability, is ongoing. As part of our participation in the FDA-sponsored Medical Device Interoperability Coordinating Council (MDICC), Dr. Goldman is chairing a committee on Clinical Needs & Clinical Landscape for Interoperability. This group has begun collecting clinical scenarios related to interoperability, and in support of that effort we posted on our mdpnp.org web site a template based on the clinical scenarios in the ICE standard. We are maintaining an index to the scenarios contributed by various sources, and those that can be shared will eventually be added to our repository as well (see **Objective 5**). Engineering requirements that are being developed under our NIH Quantum grant will also be contributed to this work and, as appropriate, to the repository.

Clinical and Engineering Requirements, Objective 7: Identify appropriate use cases to include in subsequent ICE parts.

Current work with collaborators – including the Medical Device Interoperability Safety Working Group, NIST, and various companies – is identifying use cases that could be included in subsequent parts of the ICE standard. The FDA MDICC work described above will also provide candidate scenarios for further development of ICE.

Our modeling work with Intel suggests that many ICE applications can run on standard IT networks, and even on networks that are shared with other traffic. This and other lessons from that modeling effort will also inform the development of additional ICE parts and external published guidance.

Regulatory Pathway, Objective 8: Publish jointly with FDA a summary of the results of the medical device interoperability workshop.

Completed: All talks and slides, as well as transcripts, from the workshop were published on the web (our mdpnp.org website contains links to material on the FDA website) – this constitutes publication per the intent of this objective.

Regulatory Pathway, Objective 9: Work with industry to complete development of a prototype regulatory submission to FDA, as a test case for FDA regulation of systems of integrated medical devices.

Led by Dr. Goldman, the Prototype Regulatory Submission working group (20 participants from industry, clinical care, standards development organizations, and regulatory agencies) met via weekly teleconferences throughout 2010 and 2011 to develop a detailed risk / regulatory model for an integrated "prototype" regulatory submission. This group handed off its work products to the FDA in the Spring of 2011, for further internal development at FDA, and has continued to meet under Dr. Goldman's leadership as the Medical Device Interoperability Safety (MDIS) working group. The MDIS further developed these concepts and completed a pre-IDE document, submitted to the FDA in February and discussed in a face-to-face meeting with the FDA in April. With preliminary agreement from the FDA on the core approach of this submission, it is being further refined and will be resubmitted for an official response. The MDIS group expects to continue advising the FDA on safety issues for systems of integrated medical devices.

This work has been enhanced by the active involvement of several of our MD PnP team members, and of other MDIS members, in both the AAMI Ad-Hoc Group on Health Information Technology and Interoperability and the FDA-sponsored Medical Device Interoperability Coordinating Council (see **Objective 1**).

Program Development, Objective 10: Develop an enhanced collaborative website for the MD PnP collaborators group to publicly share information.

After exploring various options, we decided to work with Open Health Tools (OHT) as an environment for publicly sharing materials and work products that we develop. We have established a medical device interoperability "project" area on OHT, and we are continuing to discuss what kinds of documents and tools we will want to share. At the HIMSS12 conference in Las Vegas, our team members attended technical and management sessions presented by OHT and made good contacts among existing OHT members.

In the past year, we have also done a major redesign of our mdpnp.org website, including the introduction of an MD PnP GitHub repository providing downloadable documents and open source code, as well as links to open source code repositories from some of our NIH collaborators.

Program Development, Objective 11: Publish on the MD PnP website a second iteration of the MD FIRE contracting language, and work with additional healthcare delivery organizations to adopt MD FIRE.

During 2011-2012 we continued to work with various organizations on updates to the MD FIRE contracting language, which was originally published in 2008. Version 1.5 was published on the mdpnp.org website in October 2011.

After considerable work with the Medical Device Interoperability Program Council at the VA and feedback from other groups, we reorganized the MD FIRE document to facilitate "cut and paste" of sections relevant to RFIs, RFPs, and contracts, and we added more references to other

related materials. We shared MD FIRE version 1.7 with several Hospital Delivery Organizations that participated in a meeting we hosted at HIMSS12 to discuss MD FIRE, implementation of the FDA's Medical Device Data System ruling, and other HIT issues common to HDOs.

In June, MD FIRE was approved by the VA's Chief Technology Officer, and version 2.0 was published on the mdpnp.org website with the VA as a signatory. Other organizations are reviewing MD FIRE for potential adoption.

Program Development, Objective 12: Stay actively involved with national health IT developments to support inclusion of medical device interoperability on the agenda.

In addition to the FDA, the MD PnP program has been working with NIST, NSF, the Office of the National Coordinator for Health IT, and the VA Office of Joint Interoperability Ventures. Recognition of the critical role of device interoperability in the national health IT agenda has increased greatly over the past year, as evidenced by the ONC adopting our NIH grant as part of the SHARP program, as well as discussion with the Federal CTO and others about how to address device clock time synchronization issues.

During the past year Dr. Goldman continued to participate in meetings of the NSF Computer & Information Science & Engineering (CISE) Advisory Committee. He has supported TATRC's participation in interagency meetings related to medical device interoperability, for example, the briefing TATRC gave on its interoperability projects to NIST in October 2011 and the NIST Cyber Physical Systems Workshop in March 2012.

The adoption of our NIH/NIBIB grant by the Office of the National Coordinator for Health IT (ONC) as an affiliate of the ONC-funded SHARP (Strategic Health IT Advanced Research Projects) program has resulted in ONC promoting our interoperability efforts on the SHARP program web site and in their standard SHARP slide deck. At HIMSS12 in February, we shared a booth with the four SHARP grantees, where we showed a new demo of our work with the PCA safety interlock. We had several good side meetings with DoD, the VA, OHT, industry, and HDOs.

Our participation in the 2011 SHARPfest meeting in Washington provided an opportunity to present our work to the other grantees and resulted in our involvement in a "Pan-SHARP" project on medication reconciliation that kicked off in December. By integrating infusion pump data into the Pan-SHARP project, we educated the SHARP grantees and ONC on important attributes of device data for the EHR and subsequent analysis of EHR data. Phase I of this project was recently completed, and there is interest in expanded Phase II work, depending on the support from ONC. Dr. Goldman will participate in a panel with other SHARP leaders at the AMIA conference in early November.

In June Dr. Goldman was invited to the FCC Chairman's mHealth Summit to represent wireless healthcare interoperability needs. He was then asked by the Chairman to be one of three co-chairs of the "mHealth Task Force" set up to develop recommendations for industry and government action to harness the potential of mobile devices to improve health outcomes and lower costs of care. In September, the Task Force released its findings and recommendations, which were presented at the Information Technology and Innovation Foundation (ITIF) panel discussion on the FCC mHealth Task Force, co-chaired by Dr. Goldman.

Dr. Goldman has been part of a group convened by the Brookings Institution to discuss capturing unique device identifiers (UDIs) in administrative health care claims. As part of the UDI Implementation Work Group, we plan to implement and test a UDI for ICE and to provide our results to the FDA.

Key Research Accomplishments

- **ASTM "ICE" standard.** A multi-institutional writing group led by the MD PnP program and convened by ASTM International – including engineers and standards experts from industry, healthcare systems, government and academia – produced Part I of the multi-part ICE standard ("Integrated Clinical Environment") that embodies a systems engineering framework to safely implement integrated multi-vendor medical device systems. These building blocks will enable flexible development and deployment of decision support and advanced monitoring systems. Part I was published as ASTM F2761-2009 (http://mdpnp.org/mdice.html). The ICE standard is being referenced now by many companies and other organizations, and it has guided and informed other related standards work, e.g. the IHE PCD domain, gap analysis of the ability of the IEEE 11073 set of standards to support the clinical use cases described in ICE, the 2010 HITSP Technical Note 905, the AAMI new work item proposal, and the new UL2800 standard.

- **Interoperability procurement language.** In June 2012 the VA signed onto the MD FIRE (Medical Device Free Interoperability Requirements for the Enterprise) interoperability procurement guide, joining the original contributing institutions – Kaiser Permanente, MGH/Partners HealthCare, and Johns Hopkins Medicine – that under MD PnP leadership issued a call for action in October 2008 to improve patient safety by recommending that medical device interoperability requirements be included as an essential element in vendor selection criteria and procurement processes. This sample procurement language has been shared with many organizations and is currently being reviewed by several groups for potential adoption. The latest version reflects input from the VA and is available on the MD PnP website (http://mdpnp.org/mdfire.php).

- **Regulatory pathway.** The MD PnP program has from its inception worked closely with the U.S. FDA to identify a regulatory pathway that will support the MD PnP concept – one which will not require re-validation or re-clearance of an entire networked system as each new independently validated device is added to the medical network. Over the past seven years we have studied and elaborated the issues and solutions surfaced by medical device interoperability stakeholders. An important step towards FDA buy-in was the three-day workshop on medical device interoperability planned by the MD PnP program in conjunction with the Continua Health Alliance and the FDA and held at the FDA in January 2010. This workshop brought together over 200 participants from stakeholder communities to explore the issues and roadmap potential solutions (http://mdpnp.org/FDA_Workshop.html).

  As follow-up to the workshop, a working group comprised of companies, standards organizations, clinical and legal participants, and the FDA has met weekly to work on the development of a prototype regulatory submission of an interoperable medical device system. This group handed off its work products to the FDA in Spring 2011, for further internal development at FDA, and has continued to meet under Dr. Goldman's leadership as the Medical Device Interoperability Safety (MDIS) working group. The MDIS further developed these concepts and completed a pre-IDE document, submitted to the FDA in February and discussed in a face-to-face meeting with the FDA in April.

- **Safety certification pathway.** The MD PnP program's collaboration with UL has resulted in mutual contributions to our ICE architecture designs and their new proposed standard (UL 2800) for certifiable safety of medical device interfaces.

- **Medical society endorsements/end-user "pull".** From March 2007 to June 2009, through MD PnP program leadership, the need for medical device interoperability was endorsed by 16 medical societies – including the American Medical Association, Anesthesia Patient Safety Foundation, the American Society of Anesthesiologists, the Society of American Gastrointestinal Endoscopic Surgeons, the World Federation of Societies of Anaesthesiologists, the Society for Technology in Anesthesia, and the Massachusetts Medical Society. These endorsements continue to be a powerful motivator for other groups considering deeper engagement. Example text:

  > *Intercommunication and interoperability of electronic medical devices could lead to important advances in patient safety and patient care, and the standards and protocols to allow such seamless intercommunication should be developed fully with these advances in mind. We also recognize that, as in all technological advances, interoperability poses safety and medico-legal challenges as well. The development of standards and production of interoperable equipment protocols should strike the proper balance to achieve maximum patient safety, efficiency, and outcome benefit.*

- **Collaborative R&D.** The Joint Workshop on High Confidence Medical Devices, Software, & Systems (HCMDSS) and MD PnP Interoperability, funded by TATRC and NSF and held in June 2007, led to extensive collaborations with the University of Pennsylvania and the University of Illinois at Urbana-Champaign. The Cyber Physical Systems program at NSF has funded each of them to work with our program to investigate safety-critical aspects of networked medical device systems. NSF awarded a five-year grant in 2010 to University of Pennsylvania that is synergistic with MD PnP efforts. Our work with DoD/TATRC SBIRs and with other collaborators has informed research priorities for NSF and other agencies.

- **CIMIT MD PnP Lab**. The CIMIT MD PnP Interoperability Lab opened in May 2006 to provide a vendor-neutral "sandbox" to evaluate the ability of candidate interoperability solutions to solve clinical problems, to model clinical use cases (in a simulation environment), to develop and test related network safety and security systems, and to support interoperability and standards conformance testing. The Lab has been used by our university collaborators to further develop demonstrations of interoperability-based patient safety improvements (improving the safety and quality of portable x-rays and of patient-controlled analgesia systems that are used for pain management). We have ongoing work in the Lab on our NIH project and projects with NIST and CIMIT investigators, and we intend to host additional inter-institutional projects there.

- **Relationships with federal agencies.** In addition to the FDA, the MD PnP program has been working with NIST, NSF, the Office of the National Coordinator for Health IT, and the VA Office of Joint Interoperability Ventures. Recognition of the critical role of device interoperability in the national health IT agenda has increased greatly over the past year, as evidenced by the ONC adopting our Quantum grant as part of the SHARP program, as well as discussion with the Federal CTO and others about how to address device clock time synchronization issues.

- **Non-DoD Funding.** In October 2010 we received a 5-year $9.9M grant from NIH/NIBIB, a significant vote of confidence in our work and achievements to date. This Phase II grant was built on the foundation of TATRC-supported research – a Phase I equivalent. We also received a $100K grant from NIST, and a $620K subcontract from the University of Pennsylvania as part of its 5-year grant from NSF Cyber Physical Systems.

In addition to the specific achievements above, the MD PnP program has continued to gain increasing traction through our collaborative relationships. The web of connections among people in our community of interest continues to generate new connections to supportive individuals in government agencies, healthcare institutions, and other organizations who are helping to further the aims of the program. CIMIT continues to provide space for the MD PnP Lab and for ten program offices.

Reportable Outcomes

200+ Meetings:

- October 2011 – September 2012 – weekly teleconference calls of the Medical Device Interoperability Safety (MDIS) working group (successor to the PRS, the Prototype Regulatory Submission working group)
- October 2011 – July 2012 – monthly teleconference calls of the VA Medical Device Interoperability Program (MDIP) Stakeholder Council (attended by Dr. Goldman as group mentor and by Ms. Whitehead)
- October – March 2012 – monthly SHARP teleconference calls (PI calls and executive officer/coordinator calls)
- October 4-5 2011 – AAMI Alarms Summit, Washington, DC
- October 7 2011 – TATRC Briefing to NIST on Medical Device Interoperability Projects
- November 1-2 2011 – NSF Computer & Information Science & Engineering (CISE) Advisory Committee, Washington DC
- November 16 2011 – NIBIB R25 Review Panel (teleconference call)
- November 29 2011 – FDA Interoperability meeting (teleconference call), as follow-up to July 2011 meeting
- December 8 2011 – kick-off of Pan-SHARP project (teleconference call)
- January 9 2012 – DoD procurement/acquisition meeting, Washington, DC
- January 9-10 2012 – Meeting of UL standards development group, Washington, DC
- January 27 2012 – Pan-SHARP Medication Reconciliation Project Meeting, Arlington, VA
- January – September 2012 – biweekly Pan-SHARP Medication Reconciliation teleconference calls
- February 1, 2, 3 2012 – series of DoD procurement/acquisition meetings, Washington, DC
- February 13-14, 16-17 2012 – AAMI standards meetings (via phone)
- February 16 2012 – FDA Interoperability committee meeting (via phone)
- February 21-24 2012 – HIMSS12 Conference, Las Vegas, NV (participated in SHARP booth and held several informal interoperability-related meetings)
- February 28 2012 – IEC 80001 standards meeting, Berlin, Germany
- March 8 2012 – NIST meeting to discuss collaborative work, Washington, DC
- March 9 2012 – FDA-hosted meeting of the Medical Device Interoperability Coordinating Council (MDICC), Washington, DC
- March 13-14 2012 – NIST Cyber Physical Systems Workshop, Chicago, IL
- March 22 2012 – DoD procurement/acquisition meeting, Washington, DC
- March 29 2012 – Meeting of Clinical Needs & Clinical Landscape working group of FDA Medical Device Interoperability Coordinating Council (via phone)
- April – September 2012 – 25 teleconference calls for the FDA MDICC activity
- April 2-3 2012 – Meeting of UL standards development group, Washington, DC

- April 12 2012 – Meeting of ASTM F29 Standards Committee, West Conshohocken, PA
- April 13 2012 – FDA meeting on Pre-IDE submission, Washington, DC
- May 7-8 2012 – Meeting of UL standards development group, Chicago, IL
- May 10-11 2012 – NSF CISE Meeting, Washington, DC
- June 6 2012 – Roundtable at FCC mHealth Summit, Washington, DC
- June – September 2012 – weekly FCC mHealth Task Force teleconferences
- July 6 2012 – AAMI Alarms Steering Committee Meeting, Washington, DC
- June 7 2012 – UL 2800 drafting committee teleconference call
- June 11-15 2012 – ISO TC121 standards meeting, Kyoto, Japan
- June 21 2012 – FDA MDICC face-to-face meeting, Washington, DC
- July 16 2012 – UDI Implementation Working Group Kick-off Meeting, Brookings Institution, Washington, DC
- July 18-19 2012 – CPS Workshop Planning Meeting organized by MD PnP, held at NSF, Washington, DC
- July 25 2012 – Open Health Tools (OHT) Architecture Council Meeting (teleconference)
- August 9-10 2012 – UL Meeting, Washington, DC
- August 13 2012 - Deloitte Information Security Program Review (teleconference)
- September 14 2012 – Open Health Tools (OHT) Meeting, Baltimore, MD
- September 24 2012 – FCC mHealth Task Force meeting, Washington, DC

18 Presentations on Medical Device Interoperability Topics:

Dr. Goldman delivered invited presentations on topics related to medical device interoperability for improving patient safety and healthcare efficiency to the following groups during the past year:

- October 4-5 2011 at AAMI Alarms Summit, Washington, DC
- October 7 2011 – as part of TATRC Briefing to NIST on Medical Device Interoperability Projects
- October 24 2011 to Regulatory Affairs Professional Society (RAPS), Indianapolis, IN
- October 25 2011 as keynote to MIT System Design and Management Program, Cambridge, MA
- November 3 2011 at OSEL (Office of Science & Engineering Lab) science seminar, FDA, Silver Spring, MD
- December 5 2011 at mHealth Summit, Washington, DC
- March 1 2012 at 3rd International Symposium of IT Networks Incorporating Medical Devices and Software, Charite Hospital, Berlin, Germany
- March 21 2012 at AAMI/FDA International Conference on Medical Device Standards and Regulation, Washington, DC
- April 18 2012 Keynote at Cyber Physical Systems Week, Beijing, China
- April 27 2012 at Fifth Annual Healthcare Informatics Symposium, Children's Hospital of Philadelphia, PA
- June 2 2012 ACCE Panel at AAMI Standards Week, Charlotte, NC
- June 18 2012 at St. Luke's International Hospital, Tokyo, Japan
- June 26 2012 at the IEEE/IFIP International Conference on Dependable Systems and Networks (DSN), Boston, MA
- June 29 2012 at IFIP 10.4 Working Group on Dependable Computing and Fault Tolerance, Rockport, MA
- July 1 2012 at IAMPOV International Symposium, Yale University, New Haven, CT

- July 10-11 2012 at the 22nd Annual INCOSE International Symposium, Rome, Italy
- September 11 2012 at MDEpiNet (Medical Device Epidemiology Network) Annual Meeting at FDA, Washington, DC

Dave Arney delivered the following presentation on medical device interoperability topics during the past year:

- April 11 2012 poster on “Device Time, Data Logging, and Virtual Medical Devices” presented at the “Design of Medical Devices” conference organized by the University of Minnesota, Minneapolis, MN

Web Site:

- www.mdpnp.org is maintained as a major communication vehicle for the program and had a major redesign this past year – provides access to ICE standard, MD FIRE contracting language, publications, posters, links to streaming video of talks from plenary meetings and from the FDA Workshop, and downloads of sharable documents and code – receives about 1,000 visits per week

Manuscripts/Publications:

- Goldman JM, Robkin M, Whitehead S. Medical Device Free Interoperability Requirements for the Enterprise (MD FIRE) V 2.0 [contracting language], August 2012; available at www.mdpnp.org.
- Goldman JM, Schrenker R, Melendez L, Hampton R, Driscoll W. Implications of the New FDA Medical Device Data System (MDDS) Regulation for Automated Clinical Documentation. *Proceedings of American Society of Anesthesiologists*: Equipment, Monitoring and Technology. October 2011.
- Medical Device Interoperability Safety Working Group (MDISWG). Pre-IDE for interoperable medical devices. FDA/CDRH submission Feb 2012.
- D Arney, JM Goldman, A Bhargav-Spantzel, A Basu, M Taborn, G Pappas, M Robkin. Simulation of Medical Device Network Performance and Requirements for an Integrated Clinical Environment. *Biomedical Instrumentation & Technology*, August 2012 – report on our work with Intel on network and computer infrastructure design and operations to support interoperability

Funding Applications Facilitated by this BAA to Date (total costs shown):

- Funded: CIMIT: $51K for FY10 program leader support
- Funded: CIMIT: $51K for FY11 program leader support
- Funded: CIMIT: $98K for FY11 support for development of a pre-clinical PCA closed-loop control application
- Funded: CIMIT: $98K for FY11 support for interoperability of portable x-ray devices with ventilators in an ICU at a VA hospital (collaboration with VA Boston)
- Funded: CIMIT: $98K for FY11 support for development of a clinical algorithm-driven interoperable smart ventilator (collaboration with Boston University)
- Funded: CIMIT: $98K for FY12 support for prototype demonstration of veterans health data exchange between 3 EHR systems (collaboration with VA HITIDE, TATRC, and NwHIN)
- Funded: TATRC: $70K for MD PnP subcontract on Moberg Research SBIR Phase II award
- Funded: TATRC: $100K for MD PnP subcontract on DocBox Inc. award

- Funded: TATRC: $785K contract for enabling medical device interoperability for the Integrated Clinical Environment
- Funded: NIST: $100K for evaluation of ICE functional requirements for medical device interoperability (standards gap analysis)
- Funded: NSF: $620K for MGH subcontract on University of Pennsylvania 5-year award for assuring safety, security, and reliability of medical device systems
- Funded: NSF: $500K for MD PnP subcontract on University of Massachusetts CPS collaborative research award
- Funded: NSF: $49K conference grant for CPS Workshop Planning Meeting
- Funded: NIH/NIBIB: $9.9M for 5-year development of prototype healthcare intranet, an open ICE platform
- Not Funded: Office of Naval Research: $11.6M for 5-year development of prototype acute critical care system of integrated medical devices for safer, monitored transport of wounded warriors from battlefield to care facility

Other: In-kind engineering support and/or contribution of equipment for the lab from Draeger Medical, Philips Healthcare, FDA, Draper Laboratory, Kaiser Permanente, University of Pennsylvania, LiveData Inc., and DocBox Inc. (valued at approximately $500,000 to date).

Conclusions

As with prior TATRC BAA support, this BAA has provided core program support that enables the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program to provide important clinically focused leadership of the growing move towards open standards and related technologies for networking medical devices to support clinical solutions for improving patient safety and healthcare efficiency. The majority of this BAA has been used for core personnel salary support, which provides the foundation to identify and access other available resources, to lead relevant standards work, and to build collaborations to achieve device interoperability objectives. These collaborations include activities and relationships with federal agencies and the White House; clinical, engineering, and IT societies; clinicians in the US, Canada, Europe, and Japan; and integrated healthcare delivery organizations like Kaiser Permanente, Johns Hopkins, Partners HealthCare, and the Veterans Health Administration.

Although we have been successful in the past year in attracting funding from several federal agencies (NIH, NSF, NIST), as well as CIMIT, all of this funding is project-specific and does not support the standards work, convening, and program infrastructure that the TATRC funding has so greatly enhanced.

Notable achievements enabled or facilitated by this TATRC support include:

- We led the development of an international standard for the Integrated Clinical Environment (ICE) and saw it through to adoption and publication by ASTM International;
- Three major healthcare delivery systems collaborated on shared interoperability contracting language under MD PnP program leadership, and a second iteration of this language was signed this year by the VA;
- Sixteen medical societies (including the AMA) have endorsed the need for medical device interoperability;
- Strong collaborations have been established with the VA and with federal agencies, including the Office of the National Coordinator for Health IT and the White House, putting medical device interoperability on the national healthcare agenda;

- The FDA held a jointly sponsored Workshop on Medical Device Interoperability, worked with an MD PnP/industry working group on defining components of a prototype regulatory submission of a system of integrated medical devices, and is reviewing the pre-IDE produced by that working group.

These activities are highly interdependent and synergistic, and TATRC support has been instrumental in providing the "program glue" to effectively leverage these synergies to realize our mutual program objectives.

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Appendix

Poster from 2012 Design of Medical Devices Conference: “Device Time, Data Logging, and Virtual Medical Devices”

Other relevant documents are linked to from the text of the report.

Device Time, Data Logging, and Virtual Medical Devices

David Arney[1,3] Pratyusha Mattegunta[1] Andrew King[3] Insup Lee[3] Soojin Park[4] Margaret Mullen-Fortino[3] Julian M. Goldman[1,2]

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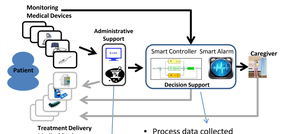
2012 Design of Medical Devices, Minneapolis, MD

Introduction

- Recent years have seen medical devices go from being monolithic to a collection of integrated systems
- Modern medical device systems have thus become a distinct class of cyber-physical systems, which we call **Medical Cyber Physical Systems (MCPS)**
- The ***goal*** of this project is a new development paradigm for the design and implementation of safe, secure, and reliable MCPS:
  - A compositional development framework for safe and secure MCPS
  - An approach to evidence-based regulatory approval and incremental certification of MCPS
  - Techniques for rigorous evaluation of clinical scenarios, both operational procedures for caregivers and device systems
  - Control-theoretic methods for the design of physiological closed-loop scenarios

MCPS: Conceptual View



- Process data collected
- Generate alarms
- Automatically initiate treatment
- Maintain Patient Records
- Actuate Treatment
- Enable continuous care

Challenges

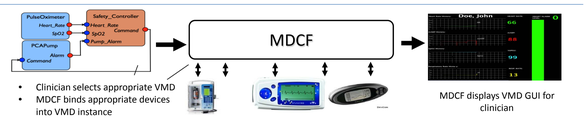
- Interoperability
- Decision Support
- Model-Driven Development
- Closed-Loop Control
- Security & Privacy

Virtual Medical Device (VMD)

VMD

- **MD PnP** (initiative for medical device interoperability) enables a new kind of medical device, a **Virtual Medical Device (VMD)**, which is composed of medical devices coordinating over a computer network.
- VMDs will not physically exist until instantiated by a hospital. The hospital will be the systems integrator.
- The Medical Device Coordination Framework (MDCF) is prototype middleware for managing the correct composition of medical devices into VMD.

Device Coordination Algorithm + Medical Device Types = Virtual Medical Device (VMD)



- Clinician selects appropriate VMD
- MDCF binds appropriate devices into VMD instance

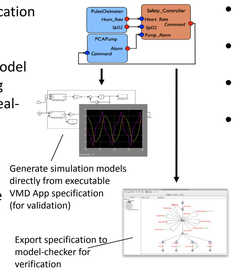
MDCF displays VMD GUI for clinician

Research Issues

Real-time support for VMD Apps

- Hard real-time communication infrastructure
- Light-weight
- Pub/sub programming model
- Support for programming clinical algorithms with real-time constraints
- Event driven
- Time triggered
- Admission control
- Guaranteed performance specified by VMD App or prevent clinician from instantiating VMD

VMD App Validation & Verification



MDCF Platform Verification

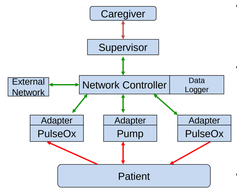
- Device connection protocols
- Device configuration protocols
- VMD setup/tear-down algorithm
- Verify that platform:
  - Correctly implements admission control
  - Correctly implements protocols

Co-Developed with NSF CNS-0930647 CPS: Medium: Collaborative Research: Infrastructure and Technology Innovations for Medical Device Coordination

MD PnP Lab @ CIMIT

- Got MDCF code to run on the BeagleBoard development boards we are using in the MD PnP Interoperability Lab
  - Enable rapid and easy deployment in our lab of prototype systems
- Involved with the AAMI standards groups for Assurance Cases and for Infusion Devices for better guidance on clinical issues and safety requirements

Medical Device Mobile PnP Prototype Platform (MD MP3)



- MD MP3 cart is a platform for the development of smart pump control algorithms
- It includes two pulse oximeters, a simulated respiratory rate monitor and an infusion pump specially modified to run software based on prior Generic Infusion Pump research that supports external control over the network
- It runs a real-time network over Ethernet hardware that guarantees message delivery with bounded latency

Device Time Study

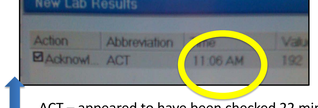
Problem

Clinical measurements and events are timed-stamped in the Electronic Medical Record (EMR). The time of measurements is important for patient care, research, and has medico-legal implications. EMR time stamping is configurable. The EMR may use the time stamp that the medical device assigns to the data, or may assign a time stamp when the data is acquired.

Despite the importance of accurate time stamps, many medical devices do not set their clock using a network time reference. In fact, these clocks are usually set manually twice a year. Also, there is no adopted standard for medical device time management, and no method to maintain consistency among all time stamps contained in the patient's EMR.

In a typical operating room, there is a wide array of different clocks in use: a clinician's watch or mobile device, a clock on the wall, a patient's monitor, anesthesia machine, or an infusion pump. Most medical device clocks are not networkable and maintain their own date and time stamps. These device clocks are manually set when the devices are put in use, typically using a personal watch or mobile device for reference. When documenting a clinical event, any of these clocks may be cited. Furthermore, the same clock is not consistently used when documenting events, which can make back-tracking through the patient's events error prone.

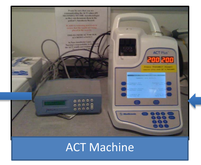
Clinical Example



EMR time-stamp error

ACT – appeared to have been checked 22 minutes after heparin administration (was actually 30 min). Could → overdose.
Cause – ACT device time incorrect
(Note - device does not use NTP)

Data protocol converter

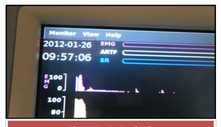


ACT Machine

Clock Sync Challenges

- Primary issues with incorrect time stamped Device Data:
  - Undermine integrity of EMR
  - May lead to inappropriate therapy
  - Complicate QA analysis
  - Introduce liability concerns
  - Security implications
- Many medical devices do not set their clock using a network time reference (e.g: NTP)
- Biomeds manually change the time on these devices twice a year, related to Daylight Savings Time
- There is no adopted standard for medical device time management
- EMR time stamping is configurable:
  - time stamp from medical device
  - time stamp when the data is acquired
- There is no method to maintain consistency among all time stamps contained in the patient's EMR

Incorrect Medical Device Clocks – Sample Pictures



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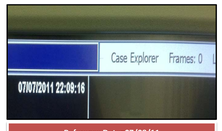
Brain Function Monitor (SED Line)



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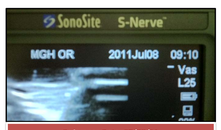
Imaging System



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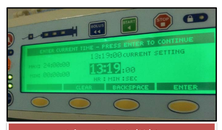
Ultrasound Machine



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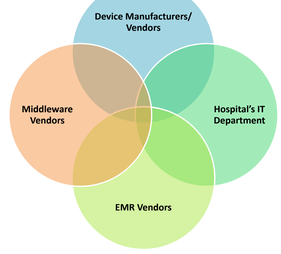
Infusion Pump

Potential Solutions for Future Discussions



- Device manufacturers could implement automatic clock-setting capability that connects to the Hospital NTP Server
- Implement time-correction in middleware or the EMR, but this leads to
- Concerns about legal and regulatory issues with altering medical device data
- Wireless or Mobile device data
- How to deal with Stored/Buffered data
- Patient ID for data coming in

Data Logging

- When adverse events happen, it is often difficult or impossible for clinicians or regulators to find the root cause of the failure.
- Devices are connected in order to:
  - accomplish meaningful use of electronic medical records
  - meet objectives for improved patient safety
- Risk of liability can be a barrier to interoperability
  - For device manufacturers
  - For system integrators
  - For Healthcare organizations
- Regulatory Compliance
  - Medical Device Data Systems (MDDS)
- ISO/IEC 80001
- The purpose of the data logger is to record low-level device data in an open, standardized, and time-synchronized manner.
- The log includes:
  - commands
  - button presses
  - location
  - device connections and disconnections
  - physiologic and technical alarms
  - physiologic data from patients
  - information about the status of devices
- Data Log supports Analysis and Playback for two complementary purposes:
  - Analysis of device interactions (debugging)
  - Analysis of adverse events involving patients (clinical)

Current Device Data Logs

- Alaris Medley Pump
- Soft Buttons
- Playback requires reconstructing device state

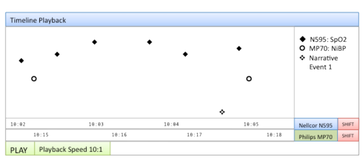
1 Off		
Off	Prev_Maint	maint_due_PCU == true or
Off	New_Patient	maint_due_PCU == false an
2 Prev_Maint		
Prev_Maint	New_Patient	maint_acknowledged == tru
3 New_Patient		
New_Patient	Same_Dept	new_patient == true
New_Patient	Set_Dept	new_patient == false
4 Same_Dept		
Same_Dept	Set_Dept	same_dept == true -> save
Same_Dept	Set_Dept	same_dept == false
5 Set_Dept		
Set_Dept	Select_Chann	department_button_pushed
6 Select_Channel		
Select_Chann	Program_Sou	channel_selected == true ->
7 Program_Source		
Program_Sour	Select_Drug	button == Guardrails
Program_Sour	Basic_Infusio	button == Basic
8 Basic_Infusion		
Basic_Infusion	Basic_Infusio	button == setRate -> rate :
Basic_Infusion	Basic_Infusio	button == setVTBI -> vtbi :
Basic_Infusion	Secondary_Ir	button == secondary
Basic_Infusion	Display_Progr	button == start

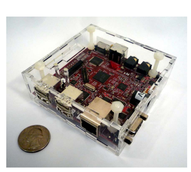
Trustworthiness of the Data Log

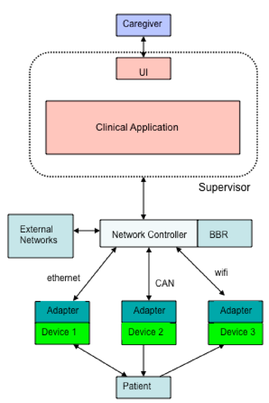
- Data logs are likely to be used as legal evidence
- Must be able to detect
  - Alterations
  - Additions
  - Deletions
- Sequence number: Additions or Deletions
- Cryptographic Signature: Alterations
- Key management and web of trust issues

Sequence #	Recorder Timestamp	Network Data	Signature

Log Playback







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